

1 UNITED STATES DISTRICT COURT  
 2 FOR THE DISTRICT OF ARIZONA  
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5 In Re: Bard IVC Filters ) MD-15-02641-PHX-DGC  
 6 Products Liability Litigation )  
 7 ) Phoenix, Arizona  
 8 ) May 23, 2018  
 9 ) 1:00 p.m.  
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BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

(Jury Trial - Day 6 - P.M. Session)  
 (Pages 1277 through 1347, inclusive.)

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5-23-18-MD 15-2641-Jones v Bard-Jury Trial-Day 6

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## I N D E X

| <u>WITNESS:</u>     | <u>DIRECT</u> | <u>CROSS</u> | <u>REDIRECT</u> | <u>RECROSS</u> |
|---------------------|---------------|--------------|-----------------|----------------|
| NATALIE WONG        |               |              |                 |                |
| By Video Deposition |               |              |                 |                |
| (Resumed)           | 1281          |              |                 |                |
| ALFRED JONES        |               |              |                 |                |
| By Mr. O'Connor     | 1282          |              | 1295            |                |
| By Mr. Rogers       |               | 1287         |                 |                |
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| CHRISTOPHER SMITH   |               |              |                 |                |
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| DONNA-BEA TILLMAN   |               |              |                 |                |
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INDEX OF EXHIBITS

| <u>EXHIBIT</u> |   | <u>RECEIVED</u> |
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| 677            | Filter - Fracture Analysis August 2010, Reporting range 7/1/05 - 8/31/10, G2, G2X, and Eclipse  | 1297            |
| 1009           | 4/6/2004 Memo from Peter Palermo to Doug Uelmen Re: "Remedial Action Plan - BPV Recovery Nitinol Vena Cava Filter", Including the Remedial Action Plan SPA 04-03-01 on the Recovery Filter, dated 3/26/2004 | 1297            |
| 1014           | 6/11/2004 Memo from Pete Palermo to Doug Uelmen Re. "Remedial Action Plan BPV Recovery Filter - Migration"  | 1297            |
| 1018           | 9/27/2004 Memo from Pete Palermo to Doug Uelmen Re: "Remedial Action Plan BPV Recovery Filter - Migration (SPA-04-05-01)"   | 1297            |
| 1022           | Failure Investigation Report on the Recovery Filter Migration, FIR-04-12-01 Rev. 00   | 1297            |
| 1140           | Presentation titled Filter-Fracture Analysis  | 1297            |

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| 5126 | Guidance for Industry and FDA<br>Reviewers/Staff - Guidance for<br>Cardiovascular Intravascular<br>Filter 510(k) Submissions  | 1341 |
| 7753 | 2014 Draft FDA Guidance re<br>Benefit-Risk Factors When Determining<br>Substantial Equivalence in Premarket<br>Notifications 510k with Different<br>Technological Characteristics | 1331 |
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P R O C E E D I N G S

THE COURT: Ladies and Gentlemen, Nancy mentioned to me that one or more of you asked whether it would be permissible for you to stand up or move around during a video to stay wide awake and attentive, and the answer is yes. If you are having any trouble focusing, just stand up, whatever you need to do to stay focused. And we'll try to continue to keep videos to a minimum.

01:01PM

MR. CLARK: How about the lawyers?

THE COURT: You guys have to stay seated.

01:01PM

Actually, you don't.

All right. Let's go ahead and continue with the Wong deposition.

(Video testimony of Natalie Wong resumed.)

MR. CLARK: Your Honor, I believe we have resolved our difficulties with the Chodos transcript and should be able to continue with that right now.

01:11PM

THE COURT: All right.

(Video testimony of David Chodos, M.D. played in open court.)

01:12PM

MR. O'CONNOR: Your Honor, at this time we're going to call Alfred Jones.

THE COURT: If you want to stand up, Ladies and Gentlemen, while he's coming in, feel free.

THE COURTROOM DEPUTY: Mr. Jones, if you will please

01:39PM

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1 come forward and raise your right hand, sir.

2 (The witness was sworn.)

3 THE COURTROOM DEPUTY: Could you state and spell your  
4 name for the record.

5 THE WITNESS: Alfred Jones. A-L-F-R-E-D, J-O-N-E-S. 01:39PM

6 THE COURTROOM DEPUTY: Thank you, sir. Please come  
7 have a seat.

8 MR. O'CONNOR: May I proceed, Your Honor?

9 THE COURT: You may.

10 ALFRED JONES,  
11 called as a witness herein, having been duly sworn, was  
12 examined and testified as follows:

13 DIRECT EXAMINATION

14 BY MR. O'CONNOR:

15 Q. Will you introduce yourself to the members of the jury,  
16 please? 01:39PM

17 A. Yes. My name is Alfred Jones.

18 THE COURT: Mr. Jones, could you get a little closer  
19 to the mic?

20 BY MR. O'CONNOR: 01:40PM

21 Q. May I call you Alfred?

22 A. Yes, you may.

23 Q. Where are you from?

24 A. Savannah, Georgia.

25 Q. And have you been there most of your life? 01:40PM

~~5-23-18-MD 15-2641-Jones v Bard-Jury Trial-Day 6-A. Jones-Direct~~

1 A. Yes, sir. Pretty much.

2 Q. How old are you today?

3 A. 52.

4 Q. Are you married to Doris Jones?

5 A. Yes, I am.

01:40PM

6 Q. How long have you been married?

7 A. 14 years, but we've been together 17.

8 Q. We heard that you actually knew Doris years before that.

9 Is that right?

10 A. Yes, sir.

01:40PM

11 Q. But it sounds as though she told us that nothing happened

12 then. Why don't you tell us your side.

13 A. Well, we grew up in the same area and went to the same

14 schools. Her father used to work on vehicles and when anyone

15 had an issue with a vehicle it was taken to her father. So

01:40PM

16 needed some work done and I took it to her father. And I

17 assume he knew I liked her. When he told me to go in and talk

18 to her, instead of going in I fixed it myself and left.

19 Q. And then you ran into her years later?

20 A. Yes.

01:41PM

21 Q. Now, Alfred, let's just go right to August 24, 2010.

22 First of all, we have heard testimony that Doris has

23 had various health issues, including issues with ulcers and GI

24 bleeding. Is that true?

25 A. Yes, it is.

01:41PM

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1 Q. Do you recall when she was hospitalized on August 24, 2010?

2 A. Yes, I do.

3 Q. And why don't you tell us about that. She went to the  
4 hospital and then eventually was there a clot discovered?

5 A. Yes. After she had the surgery for the bleeding ulcers,  
6 while she was still under the drugs, she began to get swelling  
7 and that's when they discovered there were a clot.

01:41PM

8 Q. Swelling in her ankle?

9 A. Right above the ankle, more near the calf area.

10 Q. Were you present the whole time with Doris?

01:42PM

11 A. Yes, I was.

12 Q. At some point in time was there discussion about placing a  
13 Bard Eclipse Filter?

14 A. Yes, it was.

15 Q. And how was Doris during that time when there was a  
16 discussion about the filter?

01:42PM

17 A. She was more or less in and out due to the pain medication  
18 they were giving her at that time.

19 Q. Did you have conversations with the doctor?

20 A. Yes, I did.

01:42PM

21 Q. And based upon your conversations, did you agree to have  
22 Doris undergo implantation of the filter?

23 A. Yes, I did.

24 Q. At that time, did you have any reason to know or believe  
25 that the filter may migrate, tilt, or fracture?

01:42PM

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1 A. No, I did not have any idea at all.

2 Q. Did you have an understanding how long the filter was  
3 intended to be in Doris?

4 A. My understanding was that she would need to have that  
5 filter in for basically the remainder of her life.

01:42PM

6 Q. And how did you feel about that?

7 A. Well, really, I wasn't too pleased by it but if it was  
8 going to save her life or make it prolonged to where she could  
9 live longer, then I was with anything that was going to make  
10 her stay with us.

01:43PM

11 Q. Now, at some point in time Doris had problems with that  
12 filter. Is that correct?

13 A. Yes, she did.

14 Q. And I want to fast forward to April 21/22 of 2015. Do you  
15 recall that time period?

01:43PM

16 A. Yes.

17 Q. And why don't you explain to the members of the jury what  
18 you recall about that.

19 A. This particular day she was at work and was having some  
20 issues. And they sent her to the hospital via ambulance. I  
21 was called to meet her there. When I got there, they examined  
22 her. They found out that the filter had fractured and they was  
23 going to need to remove the filter.

01:43PM

24 Q. And how did Doris -- how was she about that? Do you  
25 recall?

01:44PM

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1 A. Well, she wasn't really too pleased by it because she was  
2 under the same impression that I was, that it was going to be  
3 there for her life and that it was there to save her. And then  
4 when she found out that it had fractured, and she just was like  
5 I guess numb would be the word for it.

01:44PM

6 Q. Did you learn that a fragment of that filter had embolized  
7 or had moved up through the circulatory system through her  
8 heart and into her pulmonary artery?

9 A. Yes. That's when they told me that they was going to need  
10 to remove. So once they did the removal of what they could  
11 they said they couldn't remove the other. And I asked, well,  
12 why? And they said that it was better left where it was at  
13 because it would have -- the way they would have had to try to  
14 remove it would have caused her more damage and even death  
15 compared to just leaving it where it was at.

01:44PM

01:45PM

16 Q. Now, going back in 2010 when Doris had the Bard Eclipse  
17 Filter implanted, did you have any reason to expect that some  
18 day you would be back in the hospital because that filter  
19 fractured and embolized?

20 A. No.

01:45PM

21 Q. How is -- we heard that Doris now is taking care of her  
22 three granddaughters.

23 A. Yes, she is.

24 Q. And how does she, from your perspective, how is she these  
25 days knowing that she has that fragment in her lung?

01:45PM

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1 A. Well, I can't speak medically, but I guess it's most like  
2 any other person. You have your good days; you have your bad  
3 days. But for the most part, with that knowledge and her not  
4 really speaking with us about it, you know her, you can see the  
5 difference in how she do things, or how she carry herself as  
6 far as she's not that real out, outgoing person she used to be  
7 but she still has a smile. She still enjoys being with the  
8 kids. But you can tell deep down inside that she's really  
9 worried about it.

01:45PM

10 Q. Do you have any reason to believe she's afraid with the  
11 filter fragment in there?

01:46PM

12 A. Yes. Of course I do. And because when she do talk with us  
13 about it she breaks down. She cries. She wants to be by  
14 herself. She doesn't want to really discuss it but she  
15 sometimes just kind of like fall back and try to put the best  
16 on the outside, I guess would be the best wording for it.

01:46PM

17 Q. Let me check one thing.

18 MR. O'CONNOR: That's all I have. Thank you, Your  
19 Honor.

20 Thank you, Alfred.

01:46PM

21 THE COURT: All right. Cross-examination?

22 MR. ROGERS: Yes, Your Honor.

23 CROSS-EXAMINATION

24 BY MR. ROGERS:

25 Q. Good afternoon, Mr. Jones.

01:47PM

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1 A. How are you?

2 Q. I am well. Thank you. I hope you are.

3 A. Yes. For the most part I am, yes.

4 Q. Mr. Jones, you and I have not had a chance to meet but I  
5 need to ask you just a few questions if that's okay with you.

01:47PM

6 A. Yes, sir.

7 Q. Mr. Jones, this is kind of a silly question to start with,  
8 but you currently live in the same home with your wife, Doris,  
9 right?

10 A. Yes, I do.

01:47PM

11 Q. And who else is in that home?

12 A. Our daughter Shanice and her two children.

13 Q. And when you are there at the house, do you try and help  
14 Doris out as much as possible?

15 A. Of course. Yes, I do.

01:47PM

16 Q. And do you help Doris out with watching the grand kids?

17 A. For the most time, I do. Sometimes it's more or less I do  
18 duties around the house as far as the dishes, help with the  
19 clothing, help get them dressed, help her feed them for that  
20 part.

01:48PM

21 Q. But you do try and help out with the grand kids?

22 A. Yes. Definitely.

23 Q. Are you working right now, Mr. Jones?

24 A. Yes, I am.

25 MR. O'CONNOR: Objection.

01:48PM

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1 I was going to say objection, irrelevant. But the  
2 answer came.

3 MR. ROGERS: I'm sorry. Is it withdrawn?

4 MR. O'CONNOR: Well, no, I mean, I do have an  
5 objection that that's not relevant.

01:48PM

6 THE COURT: Are you making the objection? I can't  
7 tell.

8 MR. O'CONNOR: Objection. Irrelevant.

9 THE COURT: Sustained.

10 MR. ROGERS: May I respond, Your Honor?

01:48PM

11 THE COURT: Yes.

12 MR. ROGERS: Your Honor, I'm just trying to establish  
13 how much time Mr. Jones spends in the home.

14 THE COURT: You can ask that question.

15 MR. ROGERS: I will be glad to rephrase.

01:48PM

16 BY MR. ROGERS:

17 Q. Mr. Jones, can you tell the jury how much time you spend in  
18 the home currently?

19 A. Over a full day, I'm normally home half of the time.

20 Q. Okay. Thank you.

01:48PM

21 And Mr. Jones, let me turn your attention now to the  
22 2010 hospital admission when your wife got the IVC filter.  
23 Okay? And Mr. Jones, you were there for that admission, right?

24 A. Yes, I was.

25 Q. And I believe you were the person who actually spoke some

01:49PM

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1 with the doctor who was going to implant the filter, is that  
2 correct.

3 A. Yes, sir.

4 Q. Could we pull up Exhibit 8062, please?

5 MR. ROGERS: Your Honor, I'd like to move 8062 into  
6 evidence.

01:49PM

7 THE COURT: Any objection?

8 MR. O'CONNOR: No objection.

9 THE COURT: Admitted.

10 MR. ROGERS: May we display, Your Honor?

01:49PM

11 THE COURT: You may.

12 BY MR. ROGERS:

13 Q. Mr. Jones, can you see that document there on the screen?

14 A. Yes, sir, I can.

15 Q. And Mr. Jones, do you remember -- well, first of all, let  
16 me ask you, there's a signature there on the left-hand side.

01:49PM

17 MR. ROGERS: And Scott, if you could blow that up I'd  
18 appreciate it.

19 BY MR. ROGERS:

20 Q. But Mr. Jones, is that signature on the left-hand side, is  
21 that your signature?

01:49PM

22 A. Yes, it is.

23 Q. And is this a document that you signed before your wife  
24 underwent the procedure to have the filter implanted?

25 A. Yes, it was.

01:50PM

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1 Q. And did you have a chance to talk with the doctor, Dr.  
2 Avino, who was going to do this procedure?

3 A. Yes, I did.

4 Q. And can you tell us what he told you about this procedure  
5 and whether or not there were any potential risks with this  
6 procedure?

01:50PM

7 A. Yes, I will.

8 When I signed this particular sheet of paper, the  
9 risks that were explained to me was about the procedure or  
10 surgery, or however they implanted it. He told me that it  
11 would have been normal risk just like with any other procedure.  
12 He had done it before. It shouldn't be an issue. And I felt  
13 confident that he knew what he was talking about. He was the  
14 physician. He knew what he was doing so I had no need to worry  
15 about anything.

01:50PM

01:50PM

16 Q. At this point in time did you understand that your wife had  
17 a blood clot in her leg?

18 A. Yes, I did.

19 Q. Did you also understand that she needed to have this  
20 surgery to fix the bleeding ulcers that she had?

01:51PM

21 A. Yes.

22 Q. And did Dr. Avino explain to you that your wife had a risk  
23 of something called a pulmonary embolism, a blood clot, going  
24 to her lung?

25 A. Yes.

01:51PM

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1 Q. Did he explain to you that that was potentially something  
2 that could be deadly for your wife?

3 A. Speaking of the blood clot, yes.

4 Q. And based on that, did you perceive that there was a  
5 benefit to your wife to have this filter inserted so that it  
6 might catch a blood clot if it was headed to your wife's lungs?

01:51PM

7 A. Again, according to the doctor, I did believe that was to  
8 be the right route to take.

9 Q. And Mr. Jones, did you have any understanding that this  
10 filter was a filter that could be removed at a later date?

01:51PM

11 A. No, sir, I did not have that understanding.

12 Q. And that was not explained to you?

13 A. No, sir.

14 Q. Did you talk with anybody about this procedure or the  
15 device that was going to be implanted in your wife other than  
16 Dr. Avino?

01:52PM

17 A. No, sir, I did not.

18 Q. Because as I understood your prior testimony, did you trust  
19 Dr. Avino to do the right thing by your wife?

20 A. Yes, I did.

01:52PM

21 Q. And is that why you signed this consent form?

22 A. Yes, sir. And she was in a lot of pain. I love my wife  
23 and I wanted her to be here with me.

24 Q. Mr. Jones, let's move forward in time, if you would, to  
25 2015 when your wife had the procedure to have the filter

01:52PM

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1 removed. Do you remember that?

2 A. Yes, I do.

3 Q. And do you remember a doctor named Dr. Kirsten Nelson?

4 A. I believe that was the doctor that did the removal.

5 Q. And did you have a chance to meet her and talk with her  
6 before she did the removal procedure?

01:52PM

7 A. Yes, I did.

8 Q. And based on that conversation, did you understand that  
9 your wife did have this metallic strut that was in her left  
10 lung? Is that right?

01:53PM

11 A. Yes.

12 Q. Did Dr. Nelson explain to you that there were any potential  
13 future risks because of that fragment in her lung?

14 A. Well, not word for word. There were a risk for it being  
15 there but she did say it was a danger to her. But she,  
16 herself, could not perform the surgery and it was best to be  
17 left alone.

01:53PM

18 Q. And Mr. Jones, do you remember getting deposed in this  
19 case? Do you recall that?

20 A. Getting who?

01:53PM

21 Q. I'm sorry. Do you remember when you went to a law office  
22 or a conference room somewhere in Savannah and people asked you  
23 questions about this case?

24 A. Yes, I do.

25 Q. And that's typically called a deposition. And you can

01:53PM

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1 remember giving that?

2 A. Yes.

3 Q. And do you remember you were under oath when they asked you  
4 questions at that time?

5 A. Yes.

01:54PM

6 MR. ROGERS: Scott, if you would, can you pull up Mr.  
7 Jones' deposition, Page 36, Lines 23 on to 25.

8 BY MR. ROGERS:

9 Q. And Mr. Jones, can you see that okay on your screen?

10 A. Yes.

01:54PM

11 Q. And Mr. Jones, I'm just going to read this. If you follow  
12 along with me I'd appreciate it. And the question is: Did  
13 she, and that refers to Dr. Nelson. If you want to look at  
14 more of this to make sure that's right we'll be glad to do  
15 that. But the question said: Did she discuss at all any  
16 future risks related to leaving the strut implanted?

01:54PM

17 And your answer was: None that I can recall.

18 Did I read that correctly?

19 A. Yes, you read it correctly.

20 Q. Mr. Jones, did Dr. Nelson ever tell you your wife would  
21 need to have some sort of procedure to have that strut removed  
22 later on?

01:54PM

23 A. No, she didn't.

24 Q. And Mr. Jones, since you talked with Dr. Nelson about that  
25 strut that was in your wife's heart -- excuse me -- in your

01:55PM

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1 wife's lung, have you had any conversations with any other  
2 doctors yourself about that strut?

3 A. No, sir.

4 Q. No further questions, Mr. Jones. Thank you.

5 THE COURT: Redirect?

01:55PM

6 REDIRECT EXAMINATION

7 BY MR. O'CONNOR:

8 Q. We heard testimony from doctors who indicated that this  
9 strut was in a dangerous place to be removed. Was that your  
10 understanding, too?

01:55PM

11 A. Yes, sir, it is.

12 MR. O'CONNOR: No more questions.

13 THE COURT: Thanks, Mr. Jones. You can step down.

14 MR. O'CONNOR: Your Honor, may Mr. Jones be excused  
15 but may he remain in the courtroom?

01:56PM

16 THE COURT: Any objection?

17 MR. ROGERS: None, Your Honor.

18 THE COURT: Yeah. That's fine.

19 MR. CLARK: For plaintiff's next witness, we call  
20 Christopher Smith. And all of the exhibits associated with  
21 this deposition have been admitted into evidence.

01:56PM

22 May I be permitted to approach with the cheat sheet?

23 THE COURT: Yes.

24 MR. CLARK: Your Honor, another one of those technical  
25 difficulties has arisen. Let me proceed with Mr. Daniel Orms

01:57PM

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1 if the Court would permit me to.

2 THE COURT: So are you saying we're going to do Orms  
3 before Smith?

4 MR. CLARK: Yes, Your Honor. I apologize. I thought  
5 we had that queued up. One second. Might have shuffled the  
6 deck the wrong way. Apologize.

01:57PM

7 Your Honor, before we proceed with this deposition,  
8 the plaintiff would like to move into evidence the following  
9 exhibits, all of which are subject to redaction, in particular,  
10 the monthly management reports that we discussed earlier this  
11 morning.

01:57PM

12 THE COURT: Before we do that, Traci, I don't show  
13 2049 as being in evidence. Do you?

14 THE COURTROOM DEPUTY: I don't show it in.

15 THE COURT: So 2049 on the Smith sheet has not been  
16 admitted.

01:58PM

17 MR. CLARK: I apologize, Your Honor. I thought it  
18 was. We would move to admit 2049. I believe we cleared all  
19 the exhibits with the defendant. We can handle that one before  
20 Mr. Smith's deposition.

01:58PM

21 THE COURT: We'll come back to that when we get to  
22 Smith. So we want to do Orms now?

23 MR. CLARK: Yes, Your Honor. Before Mr. Orms'  
24 deposition, we would move the following documents into evidence  
25 again subject to redaction: 4504, 4507, 4509, 4512, 4514,

01:58PM

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1 4522, 4528, 4532, 4533, 4534, 1009, 1014, 1018, 4552, 1022,  
2 667, 1140.

3 MR. NORTH: Your Honor, first of all, I believe Mr.  
4 Clark just said 667. That should be 677, I believe.

5 MR. CLARK: I stand corrected. Thank you, Richard. 01:59PM

6 THE COURT: Any objection?

7 MR. NORTH: Your Honor, no objections subject to the  
8 redactions we talked about this morning and further subject to  
9 redactions consistent with the Court's previous orders on other  
10 issues. 01:59PM

11 THE COURT: That's fine. All right. We'll admit  
12 these exhibits subject to those redactions.

13 MR. CLARK: For this deposition there are four  
14 exhibits. I have a cheat sheet. May I approach?

15 THE COURT: Yes. 02:00PM

16 MR. CLARK: And may I be permitted to read the  
17 background summary?

18 THE COURT: Yes.

19 MR. CLARK: In 1988, Daniel Orms received his  
20 Bachelor's degree in business with specialization in marketing. 02:00PM  
21 Mr. Orms began selling medical devices for the Johnson &  
22 Johnson subsidiary Ethicon in 1991. Mr. Orms worked for number  
23 of medical device companies selling their devices before he  
24 started working for what is now Bard Peripheral Vascular in  
25 1997 as a sales representative. He became a district sales 02:00PM

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1 manager in 2001 and then a regional sales manager in 2008.

2 During his time at Bard, Mr. Orms sold Bard's Simon Nitinol,  
3 G2, and Eclipse Filters and oversaw the district and regional  
4 sales representative who sold these filters.

5 Mr. Orms was laid off from Bard in December 2012 and  
6 is currently employed as a regional manager for Abbott  
7 Vascular, another medical device manufacturer.

02:01PM

8 THE COURT: Mr. Clark, one of the exhibits listed for  
9 this deposition is 1787. That's not in evidence.

10 MR. CLARK: Your Honor, I apologize. Our notes are  
11 crossed. I would move into evidence Exhibit 1787, which is  
12 Deposition Exhibit 13.

02:01PM

13 MS. HELM: No objection.

14 THE COURT: It's admitted. You may play the  
15 deposition.

02:01PM

16 MR. CLARK: Apologize, Your Honor. Thank you.

17 THE COURT: Counsel, is that Russian?

18 MR. LOPEZ: Can we start over, Your Honor?

19 THE COURT: Good idea.

20 MR. CLARK: We thought in the interest of time we  
21 would speed it up.

02:02PM

22 THE COURT: I thought you were playing two at the same  
23 time.

24 (Video testimony of Daniel Orms played in open court.)

25 MR. CLARK: Plaintiff is going to try again with

02:27PM

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1 Christopher Smith and would move at this time into evidence  
2 Exhibit 2049.

3 MS. HELM: No objection, Your Honor.

4 THE COURT: Admitted.

5 MR. CLARK: May I be permitted to read the background  
6 summary? And I believe the Court already has the cheat sheets.

02:27PM

7 THE COURT: Yes. Go ahead.

8 MR. CLARK: Christopher Smith was a sales  
9 representative for Bard Peripheral Vascular from 2006 through  
10 2010. He began as a territory manager and was promoted to  
11 southeastern district manager in 2008. He currently works for  
12 Medtronic Neurovascular.

02:27PM

13 (Video testimony of Christopher Smith played in open  
14 court.)

15 THE COURT: Counsel, let's stop it there, please.

02:29PM

16 Ladies and Gentlemen, we will resume at 2:45.

17 (Recess from 2:29 p.m. until 2:47 p.m.)

18 THE COURT: Thank you. Please be seated.

19 All right. Counsel, you may continue.

20 (Video testimony resumed.)

02:47PM

21 MR. CLARK: Your Honor, plaintiff calls her last  
22 witness via video, Dr. Frederick Rogers. And I'm happy to  
23 report that it is a short video. May I be permitted to read  
24 the summary?

25 THE COURT: Yes.

03:05PM

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1 MR. CLARK: By the way there are no exhibits  
2 associated with this deposition.

3 Dr. Frederick Rogers specializes in critical care and  
4 has over 37 years of experience in the field of medicine. He  
5 is board certified in surgery and surgical critical care. He  
6 graduated from the University of Vermont College of Medicine  
7 with his medical degree in 1981.

03:05PM

8 In 2008, Dr. Rogers assumed the trauma medical  
9 directorship at Lancaster General Hospital, a Level 2 trauma  
10 center, in Southern Pennsylvania. And in January of 2017 he  
11 became director of the Lancaster Hospital Clinical Research  
12 Program. He has conducted clinical research involving IVC  
13 filters for more than 20 years.

03:05PM

14 Dr. Rogers is not being presented as an expert witness  
15 by either party.

03:06PM

16 (Video testimony of Frederick Rogers, M.D. played in  
17 open court.)

18 MR. CLARK: Your Honor, may I be permitted to read the  
19 answer?

20 THE COURT: I think we all know what it was. It was  
21 the third time the question was asked. You can read it.

03:16PM

22 MR. CLARK: The answer was yes.

23 THE COURT: All right. Anything else?

24 MR. O'CONNOR: Plaintiff rests, Your Honor.

25 THE COURT: All right.

03:17PM

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1 MR. NORTH: Your Honor, at this point could we briefly  
2 approach?

3 THE COURT: Go ahead and stand up, Ladies and  
4 Gentlemen.

5 (Discussion was had at sidebar out of the hearing of  
6 the jury:)

03:17PM

7 MR. NORTH: Your Honor, at this time, just as we did  
8 in Booker, I just want to be sure the record is clear and I  
9 preserve my right to assert a Rule 50 motion. We certainly can  
10 argue it at a later time at the Court's convenience.

03:17PM

11 THE COURT: All right. The motion is deemed made.

12 MR. NORTH: Thank you.

13 (In open court.)

14 MR. NORTH: Your Honor, at this time the defendants  
15 would call Donna-Bea Tillman to the stand.

03:18PM

16 THE COURTROOM DEPUTY: Ms. Tillman, come forward and  
17 raise your right hand, please.

18 (The witness was sworn.)

19 THE COURTROOM DEPUTY: Could you please state your  
20 name and spell it for the record, ma'am?

03:18PM

21 THE WITNESS: Donna-Bea Tillman. D-O-N-N-A, hyphen  
22 B-E-A, Tillman T-I-L-L-M-A-N.

23 THE COURTROOM DEPUTY: Thank you very much. If you  
24 will please come have a seat.

25 MR. NORTH: Your Honor, if I may approach I have a

03:19PM

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1 copy of Dr. Tillman's report and reliance list for the Court.

2 THE COURT: That's fine.

3 DONNA-BEA TILLMAN,

4 called as a witness herein, having been duly sworn, was

5 examined and testified as follows:

6 DIRECT EXAMINATION

7 BY MR. NORTH:

8 Q. Good afternoon, Dr. Tillman.

9 A. Good afternoon.

10 Q. Could you tell the members of the jury where you reside?

03:19PM

11 A. I live in Columbia, Maryland.

12 Q. What is your profession?

13 A. I am a biomedical engineer.

14 Q. Do you specialize in any particular area?

15 A. Yes. I specialize in FDA regulations of medical devices.

03:19PM

16 Q. And what is your present employment?

17 A. So I work for a company called Biologics Consulting Group.

18 Q. And what sort of consulting company is Biologics Consulting

19 Group?

20 A. So we help medical device companies, biologics companies,

03:20PM

21 and pharmaceutical companies who have products that they are

22 taking in front of the FDA develop the data and evidence they

23 need to support their marketing applications.

24 Q. And prior to today, have you ever testified at a trial

25 before?

03:20PM

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1 A. This is my second trial.

2 Q. Could you tell the members of the jury about your  
3 educational background?

4 A. Sure. So I have an undergraduate degree in engineering  
5 from Tulane University and I have a Ph.D. in biomedical  
6 engineering from Johns Hopkins and I have a master's in public  
7 administration from The American University.

03:20PM

8 Q. And when did you obtain your Ph.D.?

9 A. I was at Hopkins from, let's see, 1985 to 1992, I believe.

10 Q. After you received your Ph.D. in biomedical engineering,  
11 what was your first major employment?

03:21PM

12 A. So I went to work for the government for the Consumer  
13 Products Safety Commission. That's a federal agency that's  
14 responsible for helping to ensure the safety of consumer  
15 products.

03:21PM

16 Q. And what was your position at the Consumer Products Safety  
17 Commission?

18 A. So I was a physiologist in the Health Sciences Directorate.

19 Q. What did you do as a physiologist in that commission?

20 A. So I worked on different product spaces trying to help  
21 ensure the safety of consumer products. I worked in the area  
22 of swimming pool safety, so trying to find the appropriate  
23 warning labels and information to help people understand they  
24 shouldn't dive into shallow swimming pools. I worked on  
25 playground equipment. I worked on the warning labels you may

03:21PM

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1 see on five-gallon buckets warning people children can actually  
2 drown in five-gallon buckets, a wide range of consumer  
3 products.

4 Q. How long did you stay at the Product Consumer Safety  
5 Commission?

03:22PM

6 A. I think I was there about three years.

7 Q. Where did you go after you left the Commission?

8 A. So I then went to work for the FDA.

9 Q. When did you go to work for the FDA?

10 A. I believe it was 1994.

03:22PM

11 Q. And what area of the FDA did you first work with?

12 A. So I started out as a reviewer in the Obstetrics and  
13 Gynecology Devices Branch in the part of FDA that does  
14 premarket reviews of medical devices.

15 Q. What sorts of products were you looking at at that point?

03:22PM

16 A. So obstetric and gynecology devices; women's health  
17 products; contraceptive products; products used in  
18 gynecological surgery. Pretty much anything that falls into  
19 that category.

20 Q. And what does a medical reviewer at the FDA do?

03:22PM

21 A. So I was a biomedical engineer, and so my job was to take  
22 the lead on reviewing different kinds of premarket submissions.  
23 When I started it was mostly 510(k) submissions and then other  
24 kinds of premarket submissions for different kinds of medical  
25 devices.

03:23PM

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1 Q. And how long did you hold that position?

2 A. So I was a reviewer for approximately three years.

3 Q. And then would that have taken you through approximately  
4 1997?

5 A. Yes. I think that's correct.

03:23PM

6 Q. And then in 1997, did you move to another area of the FDA?

7 A. I did. I moved into my first management position, which  
8 was in the group that did pacemakers and neurological devices.  
9 So I was the branch chief of that branch.

10 Q. And how long were you the branch chief for pacing and  
11 electrophysiology devices?

03:23PM

12 A. I think I was a branch chief for approximately three years,  
13 I would say.

14 Q. And how many people at the FDA reported to you at that time  
15 or during that period?

03:23PM

16 A. Yeah, it fluctuated a little bit but somewhere between  
17 12 -- I had 12 and 14 scientists and medical officers that  
18 worked for me during that time.

19 Q. And as the manager of the group, exactly what was your  
20 individual role or responsibility?

03:24PM

21 A. So my job was to coordinate the reviews that were performed  
22 by my branch. So to assign work when a new submission would  
23 come in I would assign that submission to one of the reviewers.  
24 When they finished their review they would make a  
25 recommendation to me, and I would review those recommendations

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1 to make sure there was consistency across the branch. And then  
2 I had basic personnel and management responsibilities as well.

3 Q. And did the submissions that you would sign off on, did  
4 those include device submissions for premarket approval?

5 A. Yes. They included premarket approvals or PMAs and 510(k)s  
6 and IDEs and a wide range of other kinds of less common  
7 submissions.

03:24PM

8 Q. And did you remain in that position for approximately three  
9 years?

10 A. Yes. I believe it was approximately three years.

03:25PM

11 Q. And after that in 2000, where did you move in the FDA?

12 A. So my next formal position was as the Deputy Director for  
13 Cardiovascular Devices. So it was sort of the next level up  
14 the administrative hierarchy. So in that position I had a  
15 number of branch chiefs that reported to me.

03:25PM

16 Q. And how long were you in that group?

17 A. So I was in that position for, once again, roughly two to  
18 three years, I would say.

19 Q. And what exactly were your responsibilities as the Deputy  
20 Director of the Division of Cardiovascular?

03:25PM

21 A. So my job was sort of similar to the branch chief job but  
22 sort of one level up. So it was to ensure consistency and  
23 quality of the reviews that came through the Division to help  
24 on allocating resources between the different branches. I also  
25 was responsible, actually had the authority to sign off on

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1 510(k) submissions when I was in that position. So I was  
2 actually the person at FDA who was the final signatory on  
3 510(k) submissions at that time.

4 Q. And in that role, what particular types of devices fell  
5 under the jurisdiction of the Division of Cardiovascular?

03:26PM

6 A. So my part of the Division included electrophysiology  
7 devices; catheters that are used to do cardiac procedures;  
8 cardiac pacemakers; I was responsible for the peripheral  
9 vascular devices branch, so it would include intravascular  
10 filters; all the monitors when you go to a hospital and get  
11 hooked up to ECGs, those kinds of devices as well.

03:26PM

12 Q. And during those years as the Deputy Director For the  
13 Division of Cardiovascular, approximately how many FDA  
14 employees reported to you?

15 A. So the branch chiefs reported directly to me and then under  
16 the branch chiefs they had their own employees. So roughly  
17 indirectly, 30 to 40 people reported to me.

03:26PM

18 Q. And what was your next position within the FDA?

19 A. So then I moved up to the level of the Office Director.  
20 And so I was the Deputy Office Director For Science and  
21 Technology, so more of a policy position.

03:27PM

22 Q. And what sort of role did you play or responsibilities did  
23 you have in that position?

24 A. So in that position it was really trying to develop policy  
25 and guidance and overall direction for the Premarket Program.

03:27PM

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1 So I was very much involved with developing guidance documents  
2 for 510(k), IDE, PMA programs. I was involved in a policy  
3 around how FDA was going to regulate medical devices software  
4 and high level questions about how FDA's Premarket Program sort  
5 of functioned at a macro level.

03:27PM

6 Q. And then in April of 2004, were you promoted to a new  
7 position?

8 A. Yes. So at that point in time, I became the Director of  
9 the Office of Device Evaluation. So I was overseeing the  
10 entire Premarket Review Program for medical devices except for  
11 the in vitro diagnostic devices which have their own office.

03:28PM

12 Q. And what was your role as the Director of the Office of  
13 Device Evaluation?

14 A. So my I had overall responsibility for the Premarket Review  
15 Program. So I was responsible for managing resources. I was  
16 responsible for creating overall review policy and direction  
17 for the staff. I was responsible for organizing -- dealing  
18 with issues that crossed between my office and the other  
19 offices so where there were issues that maybe involved  
20 premarket and post-market and compliance issues, I represented  
21 my office on those committees.

03:28PM

03:28PM

22 Q. Dr. Tillman, approximately how many FDA employees reported  
23 to you in that position?

24 A. So there were around 350 scientists and medical officers  
25 and administrative folks who worked for me at that time.

03:29PM

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1 Q. Now, how long did you remain in that position?

2 A. So I was in that position for approximately six years until  
3 2010.

4 Q. And did you leave the FDA in 2010?

5 A. Yes, I did. It was a very hard decision for me, but I have  
6 always been interested in medical device software. It's a very  
7 interesting area from a regulatory and public health

03:29PM

8 perspective. And I was approached by Microsoft. And they were  
9 developing a medical device software group. I had the

10 opportunity to go to work for them and help them figure out how

03:29PM

11 they would integrate their processes and how they would sort of

12 deal with medical device regulations. So it was a very

13 exciting opportunity for me and so I left FDA to work for

14 Microsoft.

15 Q. And for approximately how long were you with Microsoft?

03:29PM

16 A. So I was there for about two and-a-half years.

17 Q. And why did you decide to leave Microsoft?

18 A. So at that time, Microsoft decided that they were going to

19 take their health group and form a joint venture with another

20 medical device company. And they wanted me to move out to

03:30PM

21 Seattle, and that just wasn't going to be a good option for me

22 given some of my family commitments. So I left Microsoft at

23 that time.

24 Q. And what did you do after you left Microsoft?

25 A. That's when I joined my current company, Biologics

03:30PM

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1 Consulting.

2 Q. How many years total were you employed by the FDA, Dr.  
3 Tillman?

4 A. I was at the FDA for 17 years.

5 Q. Can you estimate how many premarket submissions for medical  
6 devices you may have reviewed during those 17 years?

03:30PM

7 A. So if you include the submissions I reviewed both as a  
8 reviewer and as a branch chief and then as a deputy division  
9 director and then the ones I saw as office director, I would  
10 estimate anywhere between 1 to 2,000 pre market submissions.

03:30PM

11 Q. Did those include PMAs and 510(k)s?

12 A. Yes, they did.

13 Q. And ultimately, were you the person at the FDA ultimately  
14 responsible for all premarket submissions during your last six  
15 years there?

03:31PM

16 A. With the exception of the in vitro diagnostics, yes. I was  
17 ultimately responsible for the final signoff on all premarket  
18 submissions.

19 Q. Now, tell us what you do -- well, have you been with your  
20 present company Biologics Consulting Group since 2012?

03:31PM

21 A. Yes, I have.

22 Q. And what sort of work do you do with that company?

23 A. So I work with medical device companies and both very small  
24 startup companies where an inventor might have an idea of a  
25 novel medical device and they know they have to go to the FDA

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1 but they really don't understand that process, so I help them  
2 both understand what it means to be a regulated medical device  
3 company and how to develop the kinds of data they need to  
4 support their products. And I work with companies also to help  
5 them develop quality systems, so how do they develop processes  
6 to make sure that they consistently produce quality products.

03:32PM

7 I work with clients who need help if they are having  
8 problems in the post-market setting where perhaps they have got  
9 a problem with a device and they are trying to figure out how  
10 to deal with that. So pretty much having to do with FDA  
11 regulation of medical devices I help companies in that sense.

03:32PM

12 Q. And in your present role, do you actually meet with the FDA  
13 on occasion on behalf of the these clients?

14 A. Yes. I regularly meet with FDA on behalf of my clients.

15 Q. In your present consulting work, do you actually draft  
16 labeling or Instructions For Use, proposed Instructions For Use  
17 for review or clearance or approval by the FDA?

03:32PM

18 A. So I work -- I definitely work with my clients to draft  
19 labeling. It is a very important part of any premarket  
20 submission, so I usually start with my clients where I give  
21 them examples of labeling to look at. They draft their  
22 labeling. I provide them guidance on what they need to put in  
23 that in order to make it consistent with FDA's expectations.

03:32PM

24 Q. And did you ever become involved in any capacity with  
25 inferior vena cava filters while working at the FDA?

03:33PM

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1 A. Yes. When I was at the FDA, I was the branch chief of the  
2 branch that was responsible for reviewing inferior vena cava  
3 filters. And, in fact, if you look at some of the letters from  
4 FDA relating to the 510(k)s you will see my name on them.

5 Q. Over the course of the last few years in your consulting  
6 business, what sort of medical devices have you been involved  
7 with generally?

03:33PM

8 A. So one of my major areas of focus is medical device  
9 software: When does your phone become a medical device? What  
10 kinds of medical applications, software applications are a  
11 medical device? I work a lot in radiology imaging, so software  
12 that's intended to be used to analyze radiological images and  
13 identify regions of interest.

03:33PM

14 I work a lot in the combination product space. So  
15 that is where you have a product that might include a drug  
16 component and a device component, for example, a stent that has  
17 a drug in it and novel kinds of drug delivery systems. And  
18 because of my experience at FDA, I work pretty much in almost  
19 any kind of cardiovascular medical device.

03:34PM

20 Q. As a part of your consulting work, do you also assist  
21 parties that are involved in litigation involving medical  
22 devices?

03:34PM

23 A. So that is part of what I do. I would estimate that it's  
24 about 15 percent of what I do. Most of what I do is the pure  
25 regulatory consulting, but I do do some litigation work.

03:34PM

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1 Q. Do you charge a rate for consulting work in litigation?

2 A. So I'm an employee of a company so I am paid by my company.  
3 My company bills \$500 an hour for my time, but that money  
4 doesn't come directly to me.

5 Q. Have you been involved in any other litigation on behalf of  
6 Bard?

7 A. So I also work with Bard on its transvaginal mesh  
8 litigation.

9 Q. And were you paid for that work?

10 A. Yes, I was.

11 Q. Doctor, at my request and the request of my team, have you  
12 undertaken a review of the regulatory history of Bard's IVC  
13 filters?

14 A. Yes, I have.

15 Q. And as a result of this review that you have conducted,  
16 have you reached opinions as a regulatory technical specialist  
17 in this case?

18 A. Yes. I have a number of opinions that I have documented in  
19 a report I wrote.

20 Q. Have you reached an opinion concerning the FDA's present  
21 classification of filters?

22 A. Yes, I have.

23 Q. And tell us what that opinion is, generally.

24 A. So that opinion is that FDA has classified IVC filters as  
25 Class II devices based on an understanding that they know what

03:35PM

03:35PM

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03:36PM

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1 the risks are and they can establish special controls that  
2 enable those risks to be mitigated to an appropriate level;  
3 that the benefits of those devices should outweigh the risks.

4 Q. Do you have an opinion regarding what the FDA has to find  
5 to downclassify a device?

03:36PM

6 A. Yes. I have an opinion about that.

7 Q. And what is that?

8 A. So in order to classify a device in Class II, they need to  
9 demonstrate that the device does not present an unreasonable  
10 risk of illness or injury, and that they can establish these  
11 special controls that should ensure that the device benefits  
12 outweigh its risks.

03:36PM

13 Q. As a part of your work and review of materials in this  
14 case, did you review Bard's premarket -- or Bard's submissions  
15 to the FDA regarding the G2, or the Recovery Filter, the G2  
16 Filter and the Eclipse Filter?

03:37PM

17 A. Yes. I have received and reviewed copies of all of  
18 Bard's -- well, I shouldn't say all, all of the relevant Bard  
19 filter 510(k)s.

20 Q. And did you reach an opinion about the appropriateness or  
21 adequacy of those submissions that Bard made to the FDA?

03:37PM

22 A. Yes. My opinion is that the information that was provided  
23 in the submissions was consistent with what FDA would expect to  
24 be in a 510(k) submission for a device of this type, and that  
25 it was consistent with FDA's special control guidance document

03:37PM

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1 for intravascular filters.

2 Q. And as a part of your work in this case, did you review  
3 Bard's instructions for use and promotional materials regarding  
4 the Recovery G2 and Eclipse Filters?

5 A. Yes, I did.

03:38PM

6 Q. And did you reach an opinion about the adequacy or  
7 appropriateness of those materials?

8 A. Yes. My opinion is that those materials are consistent  
9 with FDA's expectations with the information that FDA's  
10 guidance document suggests should be in filters, and that they  
11 are also consistent with what is in the labeling and what is  
12 the sort of standard expectation for filters in general.

03:38PM

13 Q. The jury has heard some testimony about the MAUDE database.  
14 Can you tell us what MAUDE stands for?

15 A. So the MAUDE database is FDA's publicly available database  
16 of adverse event reports.

03:38PM

17 Q. As a part of your work in this case, have you reached any  
18 opinions as to whether it would be appropriate for a  
19 manufacturer to include complication rate information taken  
20 from the MAUDE database in its labeling regarding a device?

03:39PM

21 A. Yes. My opinion is that it would be inappropriate for a  
22 manufacturer to include comparative information based on the  
23 MAUDE database, because the information in that database is  
24 fundamentally limited in what you can learn from it.

25 Q. Dr. Tillman, let's talk just generally, if we could, about

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1 the regulatory process or scheme developed by Congress for  
2 medical devices.

3 Did you prepare some PowerPoint slides to use as  
4 demonstrative evidence to demonstrate the various  
5 classifications of products?

03:39PM

6 A. Yes, I did.

7 Q. First of all, how many classifications have been created  
8 for medical devices?

9 A. So medical devices are broadly classified into one of three  
10 categories: Class I, Class II, and Class III.

03:40PM

11 Q. If we could bring up Exhibit 7929-1. 7929.

12 Why don't you tell us about Class I devices.

13 A. So Class I devices are the lowest risk devices. They are  
14 simple things like manual surgical instruments; tooth brushes  
15 are actually Class I medical devices. Class I devices do not  
16 require any kind of premarket submission to FDA, but companies  
17 that manufacture Class I devices still usually need to  
18 establish a quality system.

03:40PM

19 Q. What about Class II? What is involved with a Class II  
20 device and how are they differentiated from Class I devices?

03:40PM

21 A. So Class II devices are devices that are of a slightly  
22 higher risk than Class I devices. They are devices that  
23 require -- most of them require a company to submit something  
24 called a 510(k) to FDA before they can be marketed. They are  
25 subject to what we have called special controls which are often

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1 guidance documents that FDA writes. Class II devices also have  
2 to have a quality system, and the intervascular filters that  
3 we're talking about today are Class II devices.

4 Q. And what is the regulatory standard that the FDA applies to  
5 permit a Class II device to be introduced or sold on the  
6 market?

03:41PM

7 A. So a Class II device or a device that needs a 510(k) has to  
8 be shown to be substantially equivalent to a predicate device  
9 before it can be marketed.

10 MR. NORTH: If we could bring up Number 2.

03:41PM

11 BY MR. NORTH:

12 Q. Tell us what class an IVC filter falls in.

13 A. So IVC filters are Class II devices. I should say with one  
14 exception.

15 Q. What's that exception?

03:42PM

16 A. There was one IVC filter, the Bird's Nest Filter, which  
17 actually was Class III and required a PMA. The ones we're  
18 talking about today and the vast majority of IVC filters are  
19 Class II.

20 Q. Now, do Class II devices such as IVC filters require  
21 preclinical testing?

03:42PM

22 A. Yes. Most IVC filters and most Class II devices are  
23 supported by bench or preclinical testing. Some of them  
24 require animal testing, and only a very small handful of them  
25 actually require clinical data.

03:42PM

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1 Q. What about actual clinical tests? We've heard testimony  
2 about some clinical tests performed with the Bard filters. Are  
3 those generally required for Class II devices?

4 A. So only roughly 5 to 10 percent of Class II devices or  
5 510(k) devices require clinical data. So IVC filters are  
6 somewhat unique in the sense that they do require clinical data  
7 for certain types of modifications.

03:43PM

8 Q. So what is the third class of medical devices?

9 A. So Class III devices are the most novel and the most  
10 complex medical devices, and they require a submission called a  
11 premarket approval submission.

03:43PM

12 Q. What is the regulatory standard for approval of a premarket  
13 application for a Class III device?

14 A. So a PMA has to show that the device is -- that there is a  
15 reasonable assurance of safety and effectiveness. That is the  
16 regulatory standard for a PMA.

03:44PM

17 Q. Who makes the determination as to whether to seek FDA  
18 clearance or approval for a device as either under the 510(k)  
19 process or the PMA process?

20 A. So devices are put into classes by FDA. And so if a  
21 particular device, for example, IVC filters are Class II, that  
22 means that if that product meets the definition of a Class II  
23 device, then that company needs to submit a 510(k). If the  
24 device is a type that FDA requires a PMA for then that company  
25 has to submit a PMA.

03:44PM

03:44PM

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1           So companies don't get to choose whether they want to  
2 submit a 510(k) or PMA, the regulatory pathway is defined by  
3 the particular device and its indications for use.

4       Q. In this country, are the majority of medical devices  
5 brought to the market through the 510(k) process that inferior  
6 vena cava filters generally go through or through the PMA  
7 process?

03:45PM

8       A. So the vast majority of devices that go to market go  
9 through 510(k). FDA receives somewhere between 3 to 4,000  
10 510(k) submissions each year, and they receive, depending on  
11 the year, anywhere between 30 and 50 original PMA submissions.  
12 So the vast majority of new devices go to market through the  
13 510(k) program.

03:45PM

14      Q. I believe you mentioned earlier that the standard for  
15 clearance of a 510(k) device such as an IVC filter is  
16 substantial equivalence?

03:45PM

17      A. Yes. That is correct.

18      Q. And what exactly does that mean? Substantially equivalent  
19 to what?

20      A. So a device has to be shown to be substantially equivalent  
21 to a predicate device, which is a legally marketed device that  
22 has basically gone to market through the 510(k) process. I  
23 mean, that's the most common way. So you have to show that the  
24 device is substantially equivalent to another device that's  
25 already out there.

03:45PM

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1 Q. Can a new device be found to be substantially equivalent by  
2 the FDA to the predicate device even if it has new  
3 technological characteristics?

4 A. Absolutely. Many 510(k) devices and many of the  
5 submissions FDA gets are for incremental or even for fairly  
6 significant improvements to devices. And so it's not at all  
7 uncommon for a device to have different technological  
8 characteristics compared to its predicate. The basis of the  
9 510(k) program is to allow for innovation. So you have got  
10 devices out there, and as medical device companies innovate and  
11 add new features and capabilities to the new devices they make  
12 an argument the new devices are substantially equivalent to the  
13 older ones. And over time, we get more sophisticated and we  
14 get more innovative medical devices.

15 Q. If we could bring up 7758, please.

16 Are you familiar with this document that's being  
17 displayed in front of you, 7758?

18 A. I am very familiar with this document.

19 Q. And tell us what this document is, if you would.

20 A. So this is a guidance document. So this is a document that  
21 FDA prepares to help medical device companies understand what  
22 its regulations and policies are regarding a particular area.  
23 So this guidance is about the 510(k) program.

24 Q. Are these documents made publicly available by the FDA?

25 A. Yes. These documents are all posted on FDA's website.

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1 MR. NORTH: Your Honor, at this time we would offer  
2 for admission Exhibit 7758.

3 MR. LOPEZ: Objection. Hearsay, Your Honor. I don't  
4 mind cross-examination with it, but I object to the admission  
5 of the entire document as hearsay.

03:48PM

6 THE COURT: I don't know what you mean by  
7 cross-examination. You will be doing cross-examination.

8 MR. LOPEZ: Directing it -- I don't mind him treating  
9 it like a medical article but I'm going to object to admission  
10 of the entire document.

03:48PM

11 THE COURT: What's your response on hearsay?

12 MR. NORTH: Your Honor, I believe under the exception  
13 of 803.8 as a public record. It reflects the office's  
14 activities.

15 MR. LOPEZ: I think there are probably some 403  
16 reasons, too. It's a pretty dense document.

03:48PM

17 THE COURT: Well, do you have specific 403 concerns  
18 you want to express?

19 MR. LOPEZ: Just that -- well, we want to do it at  
20 sidebar?

03:49PM

21 THE COURT: If we're going to talk about 403 issues we  
22 should probably talk about them at sidebar.

23 If you want to stand up, Ladies and Gentlemen, feel  
24 free.

25 (Discussion was had at sidebar out of the hearing of

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1 the jury:)

2 MR. LOPEZ: My only hesitancy with a document like  
3 this is we're going to talk about three or four pages of it  
4 probably, each. I'm going to talk about it, too. But then you  
5 let this thing in the jury room and it allows -- just like my  
6 medical articles didn't get in.

03:49PM

7 THE COURT: Tell me what specifically is your 403  
8 concern.

9 MR. LOPEZ: That primarily it could just be -- I just  
10 think some of this could be misleading.

03:50PM

11 THE COURT: Such as?

12 MR. LOPEZ: Just, Your Honor, let me do this. Instead  
13 of answering that question, I have got some government  
14 documents, too. As long as we're going to agree these are  
15 admissible because they are public record government documents,  
16 fine. Good for the goose is good for the gander. So I'm  
17 willing to allow this to come in.

03:50PM

18 THE COURT: I don't think you get to allow it.

19 MR. LOPEZ: What?

20 THE COURT: I don't think you get to allow it.

03:50PM

21 MR. LOPEZ: Oh. I'm sorry.

22 THE COURT: You said you are going to allow it to come  
23 in.

24 MR. LOPEZ: I mean I'm not going to object.

25 THE COURT: You are not going to sustain your

03:50PM

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1 objection?

2 No, let's be specific. Do you have a reason for  
3 thinking this doesn't qualify as a government document under  
4 803.8?

5 MR. LOPEZ: No. It does.

03:50PM

6 THE COURT: So that resolves the hearsay issue. Is  
7 there something specific in it that gives you a 403 concern?

8 MR. LOPEZ: Nothing I can point out to you other than  
9 the fact that I think the best way, if I was going to maintain  
10 this, this objection, it would be because medical articles you  
11 can read. I don't mind this being admitted. Just my concern  
12 about anything like this, if the jury goes in no one has ever  
13 talked about it, no one has ever testified about it, they start  
14 thumbing through it and now all of a sudden they get testimony  
15 basically.

03:50PM

03:51PM

16 THE COURT: Let me ask you this question: Is there  
17 anything in this document about IVC filters specifically?

18 MR. LOPEZ: No.

19 THE COURT: It's just about the 510(k) process?

20 MR. LOPEZ: It is.

03:51PM

21 THE COURT: Well, okay. Well, I think it is  
22 admissible under 803.8. I'm not going to exclude it on Rule  
23 403 without some specific form of prejudice and I will do my  
24 very best to apply the rules consistently but I will need to  
25 hear objections to other documents.

03:51PM

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1 MR. NORTH: Can I ask the Court one thing quickly.

2 What time are you going to quit?

3 THE COURT: 4:20.

4 MR. NORTH: Thank you.

5 (In open court.)

03:51PM

6 THE COURT: Thanks, Ladies and Gentlemen. By the way,

7 we're going to go until 4:20 today for your information.

8 MR. NORTH: Your Honor, if --

9 THE COURT: Let me first say I'm going to admit

10 Exhibit 7758.

03:52PM

11 MR. NORTH: Thank you. Could we display it now?

12 THE COURT: You may.

13 BY MR. NORTH:

14 Q. If we could turn to Page 9 of this document, please. And

15 if we could look under the heading A, the 510(k) review

03:52PM

16 standard, that first paragraph, does the FDA announce there the

17 standard that it is applying when examining 510(k)

18 applications?

19 A. Yes, it does.

20 Q. And if you could read that first paragraph for us.

03:52PM

21 A. "The 510(k) review standard substantial equivalence of a

22 new device to a legally marketed predicate device differs from

23 the PMA review standard, reasonable assurance of safety and

24 effectiveness. The 510(k) review standard is comparative

25 whereas the PMA standard relies on an independent demonstration

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1 of safety and effectiveness.

2           Nevertheless, the principles of safety and  
3 effectiveness underlie the substantial equivalence  
4 determination in every 510(k) review."

5 Q. Now, when the FDA approves a Class III device as opposed to  
6 a Class II device through the PMA process, does the agency make  
7 an affirmative finding that that device has a reasonable  
8 assurance of safety and efficacy?

03:53PM

9 A. Yes, it does.

10 Q. And to be clear, does the FDA make that same pronouncement  
11 with regard to 510(k) devices like IVC filters?

03:53PM

12 A. No. It instead makes a determination that the new device  
13 is as safe and effective as the predicate device, which is a  
14 different finding than in a PMA.

15 Q. But does the FDA recognize that safety and effectiveness  
16 plays some role in its review process?

03:54PM

17 A. Absolutely. It states that in this guidance document. And  
18 I can tell you from my years at FDA and the many submissions  
19 that I have made since leaving them, 510(k)s are fundamentally  
20 about data and science and safety and effectiveness.

03:54PM

21 Q. Does substantial equivalence or demonstrating to the FDA  
22 that a device is substantially equivalent, does it mean that  
23 the proposed new device must share the exact same design  
24 characteristics as the predicate device?

25 A. No, it does not. As I mentioned before, it's fairly common

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1 for a new device to have different technological  
2 characteristics compared to the predicate device.

3 Q. What sort of data do manufacturers generally have to  
4 submit, or does the FDA require, to show that a new device is  
5 substantially equivalent to a predicate device?

03:55PM

6 A. So it obviously depends to a certain extent on the device.  
7 The data you need for a device that's just software is going to  
8 be different than what you need for something like an IVC  
9 filter. But the data often includes biocompatibility testing  
10 to show that the materials are appropriate; data looking at if  
11 the device is electrical, is it electrically safe; does it  
12 interfere, electromagnetic compatibility with other devices;  
13 are the mechanical properties of it appropriate; is the tensile  
14 and compressive strength appropriate; does it corrode; if  
15 there's software, is the software written appropriately and  
16 verified and validated; if it's sterile, has the company  
17 demonstrated that it can sterilize the device; if it's  
18 reusable, has the company demonstrated that somebody could  
19 actually clean it and reuse it.

03:55PM

03:55PM

20 So there's a lot of different kinds of data, and it  
21 really depends on the type of device.

03:56PM

22 Q. Now, does substantial equivalence as the FDA applies that  
23 standard, does it mean that the new device being proposed must  
24 have the exact same safety profile as the predicate device?

25 A. No. Different devices can have different risks and

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1 different benefits. The FDA just needs to find that the  
2 overall risk/benefit profile of the new device is comparable or  
3 equivalent to that of the predicate device.

4 Q. And conversely, does the new device have to have the exact  
5 same benefit profile as the predicate device?

03:56PM

6 A. No, it does not.

7 Q. Have you seen -- or let me ask you this. In making that  
8 determination, does the FDA sometimes consider unique factors  
9 about a new device such as, let's say, retrievability with an  
10 IVC filter to be an important aspect for consideration?

03:57PM

11 A. Yes. I think FDA often considers what potential benefits  
12 or if there's a new innovation that may be out there, what  
13 those characteristics are that may make a new device different  
14 from the predicate device. So it absolutely considers  
15 differences between the new device and old device in terms of  
16 innovative new features and capabilities.

03:57PM

17 Q. Have you seen instances where the FDA would clear a new  
18 device even though it might have more of a certain type of  
19 complication than the predicate device?

20 MR. LOPEZ: Objection, Your Honor. Not in the report.

03:57PM

21 THE COURT: Is that in the report, Mr. North?

22 MR. NORTH: I think it is, but I'm going to move on  
23 because I can't find the cite easily.

24 BY MR. NORTH:

25 Q. If we could bring up Number 7753. Can you identify what

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1 this is, Dr. Tillman?

2 A. This is another FDA guidance document, and this one is  
3 about how does the FDA look at risk and benefit when it's  
4 determining whether a new device is substantially equivalent to  
5 a predicate device.

03:58PM

6 Q. And are you familiar with this document?

7 A. I am.

8 Q. It indicates --

9 MR. LOPEZ: Your Honor, before -- I don't think this  
10 is identified on her reliance list or discussed in the report.

03:58PM

11 THE COURT: Mr. North, could you show me where that  
12 is?

13 MR. NORTH: Yes, Your Honor, on Pages 39 and 40 of the  
14 report itself and on Page 40 of the reliance list.

15 MR. LOPEZ: I withdraw my objection, Your Honor.

03:58PM

16 THE COURT: All right.

17 BY MR. NORTH:

18 Q. This indicates that it's a draft guidance. What does that  
19 mean, Dr. Tillman?

20 A. So the way FDA publishes guidance documents is it develops  
21 a draft guidance which reflects its current practices and  
22 procedures. It publishes that and then it gives the industry  
23 and other interested parties the opportunity to comment on that  
24 draft guidance, and then it takes those comments and publishes  
25 a final guidance document.

03:59PM

03:59PM

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1 MR. NORTH: Your Honor, at this time we would offer  
2 Exhibit 7753 as an exhibit.

3 MR. LOPEZ: I'm going to object, Your Honor, because  
4 of the date on this is not applicable to any date that's  
5 relevant in this case.

03:59PM

6 THE COURT: I think you need to address that, Mr.  
7 North.

8 MR. NORTH: Your Honor --

9 THE COURT: With testimony.

10 MR. NORTH: I understand.

03:59PM

11 THE COURT: The foundation does not establish this is  
12 a relevant guidance document.

13 BY MR. NORTH:

14 Q. Does this document, to your knowledge, reflect new thinking  
15 on behalf of the agency?

04:00PM

16 MR. LOPEZ: Your Honor, I'm going to object. That  
17 lacks foundation, 402 -- I'm sorry -- 602 whether or not she  
18 has personal knowledge of that.

19 THE COURT: I think you need to lay foundation for  
20 that as well.

04:00PM

21 BY MR. NORTH:

22 Q. Are you familiar with the standards that the FDA applied to  
23 submissions during the year that you were in charge of all  
24 premarket submissions for the FDA?

25 A. Yes. I'm very familiar with FDA's criteria it uses to make

04:00PM

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1 risk/benefit decisions based on the 17 years I was at FDA.

2 Q. And you left the FDA in 2010?

3 A. That is correct.

4 Q. And this document is dated 2014?

5 A. Yes.

04:00PM

6 Q. Do the general standards that this document lays out in the  
7 guidance document, are those consistent with the standards that  
8 your department and group applied in the review of medical  
9 devices?

10 A. Yes. There is really nothing -- when this guidance came  
11 out I was not at FDA anymore. It basically lays out, though,  
12 the principles and the approaches FDA takes to making  
13 risk/benefit decisions that have been going on for the past, I  
14 would say, 10 to 20 years. So it is -- those FDA's approach is  
15 now available in writing for people to understand, but this  
16 reflects what FDA was doing before the document was even  
17 written.

04:00PM

04:01PM

18 MR. NORTH: Your Honor, with that foundation I would  
19 offer again Exhibit 7753 for admission.

20 MR. LOPEZ: Still going to object, Your Honor.  
21 Guidance document by its nature is the current thinking of FDA  
22 with respect to guiding industry.

04:01PM

23 THE COURT: What's the objection?

24 MR. LOPEZ: It's not relevant to any issue or any date  
25 or any event involved in this case regarding this filter.

04:01PM

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1 THE COURT: Okay. Objection is overruled. Exhibit  
2 7753 is admitted based on the testimony just received.

3 MR. NORTH: If we could display this to the jury,  
4 Your Honor?

5 THE COURT: You may.

04:02PM

6 BY MR. NORTH:

7 Q. If we could turn to Page 7, please. Page -- under "scope,"  
8 does the FDA set forth in this particular guideline, guidance  
9 document, the standard that you were talking about earlier as  
10 to how the device needs to compare, a new device needs to  
11 compare to the predicate device?

04:02PM

12 A. Yes. What this section says is that a new device does not  
13 have to be identical to the predicate device. It can have  
14 different indications for use, for example, retrievability  
15 versus permanent or it can have different technological  
16 characteristics and still be found substantially equivalent.

04:03PM

17 Q. And is that consistent with how your group applied the  
18 standards when you were with the FDA overseeing the review of  
19 medical devices?

20 A. Yes. This is how FDA has applied the standard of  
21 substantial equivalence, frankly, since the program began.

04:03PM

22 Q. If we could turn to the next page. And under the section  
23 benefits and risk factors --

24 MR. NORTH: I'm sorry. You're one page too far.

25 BY MR. NORTH:

04:03PM

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1 Q. The second sentence there, does that state anything  
2 beginning "FDA may make a determination" anything about whether  
3 the risks and benefits of the new device have to be identical  
4 to the predicate device as you were discussing earlier?

5 A. Yes. So this makes the same point that I mentioned  
6 earlier, which is that if a new device has different risks or  
7 different benefits FDA can still find it to be substantially  
8 equivalent as long as it finds that the overall risk/benefit of  
9 the two devices is comparable or equivalent.

04:04PM

10 MR. NORTH: Can we go to the following page, please?

04:04PM

11 BY MR. NORTH:

12 Q. Under the section Increased Risk/Increased Benefit, here  
13 does the agency say anything about a situation where the new  
14 device may have greater risks than the predicate device?

15 A. Yes. It says here that if the new device has greater risks  
16 than a predicate, FDA can still find it to be substantially  
17 equivalent -- SE means substantially equivalent -- if FDA finds  
18 that there's increased benefit. So if you have a device that  
19 has increased risks, if it also brings with it increased  
20 benefits, FDA may still determine that it is substantially  
21 equivalent.

04:04PM

04:05PM

22 MR. LOPEZ: May we approach, Your Honor, on this  
23 document?

24 THE COURT: Yes. You can stand up, Ladies and  
25 Gentlemen.

04:05PM

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1 (Discussion was had at sidebar out of the hearing of  
2 the jury:)

3 MR. LOPEZ: Your Honor, if there's any evidence in  
4 this case I don't know about where FDA said you can sell the  
5 Recovery, G2, the Eclipse, despite the fact that its risks are 04:05PM  
6 greater or that there's a determination that the risk/benefit  
7 is greater than a risk for a retrievable filter, this is  
8 misleading the jury. This is a 403 issue where it is just  
9 misleading the jury so he can argue something that's not going  
10 to be in the case. Unless there's something where the FDA has 04:06PM  
11 made a determination consistent with what he's talking about  
12 with his expert, it's not relevant to this case, the FDA  
13 regulatory issues in this case, and it's not fair that she  
14 should be able to testify about something that has nothing to  
15 do with these devices. 04:06PM

16 THE COURT: Okay. You have made that objection.

17 MR. NORTH: Your Honor, the plaintiff's argument from  
18 the beginning of this litigation throughout this trial is that  
19 whatever filter involved, here the Eclipse, is not  
20 substantially equivalent because of this chain of predicates 04:06PM  
21 tracing back to the Simon Nitinol because none of the later  
22 filters have the same safety profile in their view as the  
23 predicate Simon Nitinol, which began it all.

24 That's an argument that's been presented in opening.  
25 It is an appropriate rebuttal, I believe, and highly relevant 04:07PM

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1 to point out that substantial equivalence does not turn  
2 necessarily on an identical safety profile. We're not saying  
3 the FDA made that decision here. We're saying that they are  
4 suggesting we misled the FDA because we had data that the  
5 profile wasn't the same. We're entitled to say in response.

04:07PM

6 THE COURT: I understand your response, and I know you  
7 two could argue this for the next hour. I don't believe that  
8 makes this document inadmissible or the questioning  
9 inappropriate. I think you will be entirely within your rights  
10 to argue to the jury that there's no evidence the FDA made this  
11 determination. But clearly an issue in this case is whether or  
12 not these devices were substantially equivalent or not. The  
13 FDA standard outlining in my view is relevant, and you can  
14 argue it wasn't met.

04:07PM

15 But I don't think there's anything misleading about  
16 putting the standard in front of the jury. So I'm going to  
17 overrule the objection.

04:07PM

18 MR. LOPEZ: Just to make another, it's a 2014 standard  
19 we're talking about did not apply.

20 THE COURT: She's testified it's a 20-year-old  
21 standard. Now, you can argue to the jury they shouldn't  
22 believe that, but if they do then the standard in here is  
23 relevant.

04:08PM

24 MR. LOPEZ: When did she render an opinion? It's not  
25 in her report.

04:08PM

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1 THE COURT: Well, you didn't make that objection and  
2 that's in.

3 (In open court.)

4 THE COURT: Thank you, Ladies and Gentlemen.

5 BY MR. NORTH:

04:08PM

6 Q. Do we have highlighted up there the line you were just  
7 referencing?

8 A. Yes, we do.

9 Q. Is that consistent with your understanding of how the FDA  
10 applies the substantially equivalent standard?

04:08PM

11 A. It's consistent with my understanding and my experience,  
12 yes.

13 MR. NORTH: If we could turn on the same exhibit  
14 7775.014, looking under innovative technology.

15 BY MR. NORTH:

04:09PM

16 Q. Do technological improvements in a new device factor into  
17 the FDA's assessment of clearance or substantial equivalence?

18 A. Yes, they do, because FDA has sort of two missions, two  
19 related missions: One is to protect the public health, but the  
20 second is to promote access to innovative new technologies. So  
21 as part of that sort of tension between making sure the devices  
22 are safe but also making innovative technologies available to  
23 U.S. patients, FDA recognizes that sometimes when you have a  
24 new technology there may be greater risks associated with that.  
25 But if that device also potentially offers greater benefits,

04:09PM

04:09PM

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1 then FDA may be willing to accept more uncertainty around those  
2 devices.

3 Q. Who ultimately decides whether a predicate device is  
4 appropriate for a new device?

5 A. So FDA ultimately decides if a predicate device is an  
6 appropriate predicate device.

04:10PM

7 Q. Who decides whether a device, a new device raises different  
8 types of safety and effectiveness questions?

9 A. So once again, that is a finding that FDA makes as part of  
10 its substantial equivalence determination.

04:10PM

11 Q. And who decides whether the data provided or submitted by  
12 the manufacturer provides a reasonable assurance that the new  
13 device is as safe and effective as the predicate device?

14 A. So that is the finding that FDA makes in determining if the  
15 device is substantially equivalent.

04:10PM

16 Q. When does, in this process, does the FDA determine whether  
17 a new device is substantially equivalent to a predicate device?

18 A. So usually the way it works is if a company wants to sell a  
19 device or if they have a device and they make a change to it  
20 that requires a new 510(k), they submit that to FDA, gets

04:11PM

21 reviewed by a lead reviewer and perhaps some other people, and  
22 then at the end of that review process, there is a finding by  
23 FDA if the device is substantially equivalent. And the company  
24 gets a letter that basically says we have reviewed your 510(k)  
25 submission, and we have determined based on all of the data you

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1 have provided that your device is substantially equivalent to a  
2 predicate.

3 So it's a determination that's made by FDA and it's  
4 made sort of at the end of this process and documented in a  
5 letter.

04:11PM

6 Q. Can a manufacturer sell a new medical device before the FDA  
7 makes that determination of substantial equivalence?

8 A. So if the device is a type that requires FDA to review and  
9 clear a 510(k), then the company can't sell the device until  
10 after FDA has sent them that 510(k) clearance letter.

04:12PM

11 Q. After the FDA has made a finding of substantial equivalence  
12 is the agency basically done with the device, or does it play  
13 any continuing role with the device?

14 A. No, it's not done. I like to tell my clients that it's  
15 sort of like having keys to a car, or having keys to a car but  
16 if you don't have a driver's license you can't drive it. So if  
17 you get your 510(k), that's one piece of what you need to do.

04:12PM

18 But companies also have to establish quality systems that sort  
19 of define the parameters around which they manufacture the  
20 device. We also call those good manufacturing practices.

04:12PM

21 Companies have to report adverse events to FDA. Companies have  
22 to make sure that their labeling meets the labeling  
23 requirements. Companies have to determine if there's problems  
24 with their devices. They may have to do a recall.

25 And FDA is involved with all of that. FDA inspects

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1 medical device manufacturers. So 510(k) is, I tell people,  
2 sort of just the beginning.

3 Q. Let's talk about inferior vena cava filters in particular.  
4 These devices are Class II, correct?

5 A. Yes. They were originally Class III, but FDA  
6 downclassified them to Class II.

04:13PM

7 Q. That seems somewhat of a foreign term, downclassify. What  
8 does that mean in FDA parlance?

9 A. Yeah. So I mean, it's downclassification because you  
10 started with Class III and now you are Class II. So that's why  
11 we call that -- when FDA changes a classification, we broadly  
12 call that reclassification. And if you go from III to II,  
13 that's downclassifying. If you go from II to III, for example,  
14 automatic external defibrillators that are out there in case  
15 you have a heart attack to shock you, those were originally  
16 510(k) devices. FDA recently upclassified those to Class III  
17 so that's the language.

04:13PM

04:14PM

18 Q. Generally speaking, what sort of factors play into the  
19 agency's decision when it decides to downclassify a device from  
20 Class III to Class II?

04:14PM

21 A. So in order to do that, FDA has to have determined that it  
22 understands what are the risks that the device presents, so we  
23 have to have enough information and we understand the risks,  
24 what kind of risks are there, how often do they occur, is it  
25 something that the medical community has seen.

04:14PM

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1           Then once we know what the risks are how do we  
2 mitigate those risks? What are the types of tests and data,  
3 information, labeling, what are the -- we call these special  
4 controls that can be put into place to make sure that these  
5 risks are appropriately mitigated. And then if FDA believes  
6 that it knows what the risks are, it knows how they can be  
7 mitigated and it believes that the device does not present an  
8 unreasonable risk of illness or injury, then it can  
9 downclassify the device from Class III to Class II.

04:15PM

10 Q. When were IVC filters downclassified by the FDA from Class  
11 III to Class II?

04:15PM

12 A. I believe it was around 1999-ish. Sometime in that time  
13 frame.

14 Q. And as a part of your work in this case, have you had  
15 access to internal FDA documents regarding the decision to  
16 downclassify IVC filters?

04:15PM

17 A. Yes, I have.

18 Q. And how is it possible to get those documents?

19 A. So there's a law called the Sunshine Act or the Freedom of  
20 Information Act which says that as American citizens, we should  
21 have access to the information that our government uses to make  
22 decisions. And so through this Freedom of Information Act, we  
23 call it FOIA, anybody can request documents from federal  
24 agencies and federal organizations that aren't classified or  
25 where there's not some reason why they can't be produced.

04:15PM

04:16PM

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1 And so there was a Freedom of Information request made  
2 where we requested, or somebody requested, Bard requested the  
3 documents that recorded FDA's decision making process when it  
4 decided that it would downclassify IVC filters.

5 Q. If we could bring up Exhibit 5877, please.

04:16PM

6 Do you recognize this document, Dr. Tillman?

7 A. Yes. This is an FDA --

8 MR. LOPEZ: Objection, Your Honor. This is not in the  
9 report or on the reliance list.

10 THE COURT: Mr. North.

04:17PM

11 MR. NORTH: Could we approach, Your Honor.

12 THE COURT: We've got two minutes left. Let's cover  
13 something else and not keep the jury waiting on this issue.

14 MR. NORTH: Okay.

15 BY MR. NORTH:

04:17PM

16 Q. After downclassifying IVC filters, did the FDA issue or as  
17 a part of that process issue a guidance document specific to  
18 filters?

19 A. Yes, it did. It issued a special control guidance document  
20 which basically defined what the testing and the labeling  
21 information that companies needed to have in order to support  
22 an IVC filter 510(k).

04:17PM

23 Q. If we could bring up Exhibit 5126, please.

24 Are you familiar with this document?

25 A. Yes, I am.

04:17PM

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1 Q. Is that the guidance documents for IVC filters that you  
2 just referenced?

3 A. Yes, it is.

4 MR. NORTH: Your Honor, at this time we would offer  
5 for admission Exhibit 5126.

04:18PM

6 MR. LOPEZ: No objection, Your Honor.

7 THE COURT: Admitted.

8 BY MR. NORTH:

9 Q. Now, you have talked about special controls. Does a  
10 guidance document for a specific device such as this constitute  
11 a special control?

04:18PM

12 A. Yes. This particular device-specific guidance document is  
13 a special control because it was part of the basis for the  
14 decision to downclassify IVC filters.

15 MR. NORTH: Your Honor, could we display this to the  
16 jury, please?

04:18PM

17 THE COURT: Yes.

18 BY MR. NORTH:

19 Q. How does this guidance help a manufacturer such as Bard in  
20 the submission of a 510(k) for an IVC filter?

04:18PM

21 A. So this guidance document describes in detail the  
22 information that FDA expects a company to provide in its 510(k)  
23 for an IVC filter.

24 Q. Let's turn to Page --

25 MR. NORTH: Are we displaying that document?

04:19PM

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1 THE COURT: We're going to go ahead and break at this  
2 point, Mr. North.

3 Ladies and Gentlemen, we will plan to resume at 9:00  
4 in the morning. Have a good night, and we'll excuse you at  
5 this time.

04:19PM

6 (Jury out at 4:19 p.m.)

7 THE COURT: Please be seated.

8 Counsel, how are we allocating video deposition time  
9 for this afternoon?

10 MR. CLARK: Your Honor, we are going to be allocating  
11 of the Wong deposition, 26 minutes to the plaintiff; 17 to the  
12 defendant. The remainder of the Chodos deposition, six minutes  
13 to the plaintiff; 14 to the defendant. Smith is 16 to  
14 plaintiff; three to defendant. Orms is 19 to plaintiff; five  
15 to defendant. Rogers is eight to plaintiff; three to  
16 defendant.

04:19PM

04:20PM

17 And Your Honor, I did kind of check my math against  
18 yours from this morning. I want to make sure I'm understanding  
19 how you track that. I saw about a 20-minute discrepancy. Did  
20 Your Honor assign the Wong time to the plaintiff at that time  
21 subject to revision, or did you stop your counting before Wong  
22 started? Because it seemed like --

04:20PM

23 THE COURT: You gave me a Wong allocation just before  
24 lunch, right?

25 MR. CLARK: I don't believe we did.

04:20PM

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1 THE COURT: You gave me some allocation. You gave me  
2 some allocation before lunch.

3 MS. HELM: It was Nelson and the six minutes of  
4 Chodos. And we did not give you the Wong allocations.

5 THE COURT: I didn't subtract it from -- all of the  
6 Wong time this morning was attributed to you then.

04:21PM

7 MR. CLARK: That would explain it.

8 THE COURT: So how much time from this morning from  
9 Wong goes to defendants?

10 MR. CLARK: That would be hard to estimate. It was  
11 26:17, so I think that's roughly 60/40, something like that.

04:21PM

12 THE COURT: So what did you just give me when you gave  
13 me 17 minutes to defendant, the first one you gave me?

14 MR. CLARK: 17 and 10, Your Honor, I had -- I don't  
15 have a 17 and 10.

04:21PM

16 THE COURT: No. No. You gave 17 minutes to defendant  
17 on one of the depositions you just discussed. You gave me -- I  
18 was just writing down the amount allocated to defendants  
19 because I subtract that from your time. You gave me 17  
20 minutes, 14 minutes, three minutes, five minutes, and three  
21 minutes.

04:22PM

22 MS. HELM: 17 was Wong, Your Honor.

23 THE COURT: So is 17 just Wong in the afternoon?

24 MR. CLARK: No, Your Honor. Unfortunately we don't  
25 have a way of really tracking whose portion is played when they

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1 span the gap.

2 THE COURT: What's the total from Wong that goes to  
3 the defendants?

4 MR. CLARK: 17.

5 THE COURT: I'm going to subtract that now. So that  
6 will even it up. It will come out of your afternoon time but  
7 it comes out of your time.

04:22PM

8 MR. CLARK: That makes sense. I'm sorry for the  
9 confusion.

10 THE COURT: Okay. Give me just a minute.

04:22PM

11 Okay, Counsel. I add up a total of 42 minutes this  
12 afternoon that is deposition time allocated to defendants,  
13 including the Wong time if you want to check my math. Is that  
14 what you get, too, Ms. Helm?

15 MS. HELM: Yes, Your Honor.

04:23PM

16 THE COURT: Give me just a minute then.

17 MR. COMBS: That's correct, Your Honor.

18 THE COURT: All right, counsel. As of the end of  
19 today, plaintiff has used 22 hours, 11 minutes; defendants have  
20 used seven hours, 56 minutes.

04:24PM

21 Let me mention a couple of things. Mr. Lopez and Mr.  
22 O'Connor, when you whisper at counsel table, I can hear what  
23 you are saying. So keep that in mind. If I can hear it I'm  
24 guessing the jury can hear it, too. I can't always pick out  
25 the words but I often can.

04:24PM

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1 MR. LOPEZ: Thank you, Your Honor.

2 THE COURT: What is it that you wanted to discuss at  
3 sidebar on the Exhibit 5277?

4 MR. NORTH: The Booker trial, Your Honor. It was  
5 admitted without a disclosure objection, only a hearsay  
6 objection at the Booker trial. It was not available and had  
7 not been produced by the FDA at the time she rendered her  
8 report. She did give an opinion about that downclassification  
9 in her report at Page 27, and this document merely confirmed.  
10 But they did not object on a disclosure basis, only on a  
11 hearsay basis. And that was at Page 1387 of the Booker trial  
12 transcript.

13 THE COURT: But it's not listed in her report, right?

14 MR. NORTH: Right. It was not available at the time.

15 THE COURT: So how does the failure to object at  
16 Booker on that point somehow waive it for this trial?

17 MR. NORTH: I could be mistaken, Your Honor. I  
18 thought if things had come out in a deposition or had come out  
19 in the Booker trial with opinions or materials such as this  
20 without objection.

21 THE COURT: That's testimony. I mean, I think there's  
22 been one time, maybe two, at sidebar where we discussed it and  
23 it was testimony in the Booker trial. But I have said I'm  
24 going to hold you to the requirement on Rule 26(a)(2)(B)(iii)  
25 which is exhibits used at trial need to be part of the expert

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1 report. And if this isn't part of the expert report it can't  
2 be used. I'm not going to say that the plaintiff waived that  
3 because they didn't object in the Booker trial. If it's not in  
4 the report it's not in the report.

5 MR. NORTH: And, Your Honor, there's no exception when  
6 the document was not available to any party at the time of the  
7 reports?

04:26PM

8 THE COURT: Well, it seems to me you could have raised  
9 that in an effort to supplement the report. But there's been  
10 no supplementation of the report. It's been argued in my case  
11 management order. I said only rarely would I permit  
12 supplementation. There was no effort made, so I'm going to  
13 sustain the objection to 5277 on that basis.

04:26PM

14 MR. NORTH: Thank you, Your Honor.

15 THE COURT: We'll see you at 8:30 in the morning.

04:26PM

16 (Proceeding recessed at 4:26 p.m.)  
17  
18  
19  
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21  
22  
23  
24  
25

C E R T I F I C A T E

I, LAURIE A. ADAMS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control.

DATED at Phoenix, Arizona, this 23rd day of May, 2018.

s/Laurie A. Adams

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Laurie A. Adams, RMR, CRR